FORM PTO-1390 (REV. 11-2000) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
3868-0109P	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	
NEW	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/07904	August 14, 2000	August 27, 1999

TITLE OF INVENTION
PHARMACEUTICAL PREPARATION CONTAINING NANOSOL

APPLICANT(S) FOR DO/EO/US
HOFFMANN, Hans-Rainer; ASMUSSEN, Bodo

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau. WO 01/15669
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is transmitted herewith.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☒ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 20. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form PTO-1449(s), and International Search Report (PCT/ISA/210) with 3 cited document(s).
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:
    1.) PCT Substitute Claims Letter w/ PCT/IPEA/416, PCT/IPEA/409, amended claims and translation thereof
    2.) Zero (0) sheets of Formal Drawings

U.S. APPLICATION NO (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
NEW	PCT/EP00/07904	3868-0109P

21. ☒ The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1,040.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO..... $740.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)..... **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 0	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	14 - 20 =	0	X **$18.00**	$ 0	
Independent Claims	1 - 3 =	0	X **$84.00**	$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		None	+ **$280.00**	$ 0	
			TOTAL OF ABOVE CALCULATIONS =	$ 890.00	
Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				$ 0	
			SUBTOTAL =	$ 890.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐20 ☐30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$ 0	
			TOTAL NATIONAL FEE =	$ 890.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ 40.00	
			TOTAL FEES ENCLOSED =	$ 930.00	
			Amount to be: refunded	$	
			charged	$	

a. ☒ A check in the amount of $ **930.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:
Birch, Stewart, Kolasch & Birch, LLP or Customer No. 2292
P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Date: February 26, 2002

By _____
James M. Slattery, #28,380

/cqc

PATENT
3868-0109P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: HOFFMANN, Hans-Rainer et al.

Int'l. Appl. No.: PCT/EP00/07904

Appl. No.: New Group:

Filed: February 26, 2002 Examiner:

For: PHARMACEUTICAL PREPARATION CONTAINING NANOSOL

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

February 26, 2002

Sir:

The following Preliminary Amendments and Remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE TITLE:

Please amend the title to read as follows:

--PHARMACEUTICAL PREPARATION CONTAININGN NANOSOL--

IN THE SPECIFICATION:

Please amend the specification as follows:

Before line 1, insert --This application is the national phase under 35 U.S.C. § 371 of PCT International Application No.

PCT/EP00/07904 which has an International filing date of August 14, 2000, which designated the United States of America.--

IN THE CLAIMS:

Please amend the claims as follows:

4. (Amended) Solid pharmaceutical preparation according to claim 1, characterized in that the active substance and the chitosan derivative are present in the nanosol in almost isoionic state.

5. (Amended) Solid pharmaceutical preparation according to claim 1, characterized in that the active substance is present in the nanosol in colloidal or in nanoparticulate form.

6. (Amended) Solid pharmaceutical preparation according to claim 1, characterized in that the active substance is poorly soluble.

7. (Amended) Solid pharmaceutical preparation according to claim 1, characterized in that it contains a further polymeric carrier substance apart from the chitosan derivative.

8. (Amended) Use of a pharmaceutical preparation according to claim 1 for the production of a medicinal product.

10. (Amended) Use of a pharmaceutical preparation according to claim 8 for the production of a medicinal product that is administered as a powder, granulate, tablet or capsule.

11. (Amended) Use of a pharmaceutical preparation according to claim 8 for the production of a medicinal product which, for the purpose of administration, is dissolved or redispersed in a liquid.

12. (Amended) Use of a pharmaceutical preparation according to claim 8 for the production of a medicinal product having controlled active substance release.

13. (Amended) Use of a pharmaceutical preparation according to claim 1 for the production of a diagnostic agent.

14. (Amended) Process for the production of a pharmaceutical preparation according to claim 1, characterized in that

a) a chitosan derivative is selected according to the type and relative number of its charged groups and in coordination with the type and relative number of the charged groups of the active substance such that at a certain pH value an isoionic state or

charge equalization between active substance and carrier can be achieved in the preparation,

b) an aqueous sol containing the active substance is prepared from the chitosan derivative,

c) the pH value of the aqueous sol is adjusted such that an isoionic state results, possibly with colloidal or nano-scale active substance particles precipitating, and

d) the thus-adjusted aqueous sol is dried.

REMARKS

The specification has been amended to provide a cross-reference to the previously filed International Application.

The claims have been amended to delete multiple dependencies and to place the application into better form for examination. Entry of the above amendments is earnestly solicited. An early and favorable first action on the merits is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the application by this Amendment.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
James M. Slattery, #28,380

P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

JMS/cqc
3868-0109P

Attachment: VERSION WITH MARKINGS TO SHOW CHANGES MADE

VERSION WITH MARKINGS TO SHOW CHANGES MADE

The title has been amended as follows:

PHARMACEUTICAL PREPARATION CONTAINING NANOSOL

The claims have been amended as follows:

4. (Amended) Solid pharmaceutical preparation according to [any one of the preceding claims]claim 1, characterized in that the active substance and the chitosan derivative are present in the nanosol in almost isoionic state.

5. (Amended) Solid pharmaceutical preparation according to [any one of the preceding claims]claim 1, characterized in that the active substance is present in the nanosol in colloidal or in nanoparticulate form.

6. (Amended) Solid pharmaceutical preparation according to [any one of the preceding claims]claim 1, characterized in that the active substance is poorly soluble.

7. (Amended) Solid pharmaceutical preparation according to [any one of the preceding claims]claim 1, characterized in that it contains a further polymeric carrier substance apart from the chitosan derivative.

8. (Amended) Use of a pharmaceutical preparation according to [any one of the preceding claims]claim 1 for the production of a medicinal product.

10. (Amended) Use of a pharmaceutical preparation according to [any one of Claims 8 or 9]claim 8 for the production of a medicinal product that is administered as a powder, granulate, tablet or capsule.

11. (Amended) Use of a pharmaceutical preparation according to [any one of Claims 8 to 10]claim 8 for the production of a medicinal product which, for the purpose of administration, is dissolved or redispersed in a liquid.

12. (Amended) Use of a pharmaceutical preparation according to [any one of Claims 8 to 11]claim 8 for the production of a medicinal product having controlled active substance release.

13. (Amended) Use of a pharmaceutical preparation according to [any one of Claims 1 to 7]claim 1 for the production of a diagnostic agent.

14. (Amended) Process for the production of a pharmaceutical preparation according to [any one of Claims 1 to 7]claim 1, characterized in that

a) a chitosan derivative is selected according to the type and relative number of its charged groups and in coordination with the type and relative number of the charged groups of the active substance such that at a certain pH value an isoionic state or charge equalization between active substance and carrier can be achieved in the preparation,

b) an aqueous sol containing the active substance is prepared from the chitosan derivative,

c) the pH value of the aqueous sol is adjusted such that an isoionic state results, possibly with colloidal or nano-scale active substance particles precipitating, and

d) the thus-adjusted aqueous sol is dried.

Pharmaceutical Preparation

Pharmaceutical preparations wherein an active substance is present bound to a carrier are known in the state of the art in great abundance. In the widest sense, the bond to the carrier can be understood to be purely mechanical; in a narrow sense, however, one makes use of the capacity of carrier substances to enter into special chemical or physicochemical interactions with the active substance or substances.

One category of such interactions are ionic attractive forces, which of course can only be made use of if active agent and carrier are at least partially present in a charged state. In pharmaceutical preparations, ionic bonds between active substances and carriers are used, inter alia, to preserve sparingly soluble active substances which have a low tendency of dissociation in water in their charged and molecular-disperse state, thereby obtaining a high dissolution rate. Apart from this, active agents are bonded to oppositely charged carrier polymers to enable a high active substance load of the preparation; this formulation technique is frequently used, for instance, in liposome preparations. A further variant which has been described are preparations wherein by way of the ionic bond to a charged polymer it is intended to achieve a controlled release of active substance. An example for this is the cough mixture marketed in Germany under the mark Codipront® which contains as active substance carrier complex an active substance base, Codeine poly(styrene, divinyl benzene)sulfonate, bonded to an acidic ion exchanger.

A special form of active agents bound to oppositely charged carriers are the so-called nanosols with gelatine or

collagen hydrolysates as carriers, which are described by the firm of Alfatec-Pharma GmbH in various patents and published applications, e.g., in the documents DE 41 40 195, DE 41 40 178 and DE 41 40 179. Here, one makes use of the fact that it is easily possible to achieve the desired, isoionic state with charge equalization between carrier and active substance if gelatine or gelatine derivatives are used, thanks to the zwitterionic nature of the same, by means of a corresponding pH adjustment in the preparation. It is described that these nanosols can be used to advantage for the production of medicinal preparations both with rapid and with controlled active substance release.

However, these preparations have the disadvantage that the population has been uncertain for several years as to the possible risks of BSE infection and has increasingly been avoiding products containing gelatine, for example. Therefore, there is a need for preparations without gelatine or collagen derivatives which have the same advantages as, for example, the gelatine-based nanosols described.

It is thus the object of the present invention to provide a pharmaceutical preparation without gelatine or the like, for charged active substances, in which the active substance is present bonded to an oppositely charged carrier.

The object is achieved by a pharmaceutical preparation according to Claim 1.

It was surprisingly found that using chitosans as carriers it is possible to produce so-called nanosols wherein the active substance is present stabilized in a state almost isoionic with the carrier, and that these nanosols are highly suitable for the production of medicinal products.

The preparation of the present invention contains according to Claim 1 at least one pharmaceutical active substance, which is at least partially present in a charged state, i.e. the active substance is capable of forming an ionic state and at least part of the active substance molecules are present in that ionic state.

For a definition of a nanosol, reference is made to DE 41 40 195.

Considered as chitosan derivatives in the spirit of the invention are all modified and unmodified deacetylation products of chitin which still possess a polyglucosamine base structure. The charge opposite to that of the active substance, which is demanded according to the present invention, refers to the net-charge of the carrier used. Thus there may also be charges in the chitosan derivative that are like that of the active substance as long as they are overcompensated by the opposite charges.

In fact, in one of the preferred embodiments there is an active substance with a positive charge that is bonded in the nanosol to a chitosan derivative with negative total charge. Such a chitosan derivative may, for example, be a zwitterionic, partially sulfated chitosan.

In a further, also preferred, embodiment, the active substance is present in a negatively charged state and is bound in the nanosol to a positively charged chitosan derivative, i.e. in the most simple case to an unmodified chitosan. Here, too, an active substance may well be present in a partially undissociated form and may even possess some charges that are like that of the chitosan derivative as long as its net-charge is opposite, i.e. in this case negative.

Preferably, the active substance is present in the nanosol in a colloidal or nanoparticulate distribution, i.e. with an average particle size of at maximum about 500-1000 nm, as far as it is possible to detect a phase boundary between active substance and carrier phase at all. In particular, poorly soluble active agents can be incorporated in this way in pharmaceutical preparations from which they can be quickly released.

The preparations according to the present invention will as a rule contain further auxiliary agents which are commonly used in the pharmaceutics technology and are known to those skilled in the art. These active auxiliary agents may, for example, be further polymeric or non-polymeric carrier substances, but also stabilisers, surfactants, disintegration promoters, antioxidants, dyes, pigments, flavours, sweeteners or other taste-improving agents, binders, lubricants etc. In a preferred embodiment, the preparation contains a further polymeric carrier substance. This can be required, for example, in order to increase the loadability of the nanosol with active substance or in order to modify the release properties of the preparation. Appropriate formulation techniques are likewise known to those skilled in the art.

In accordance with the invention, the herein disclosed pharmaceutical preparations are used for making medicinal products or diagnostic agents. A preferred use of the preparation consists in the production of medicinal agents which are administered as capsules, tablets, powders or granulates, or, like instant preparations, are first dissolved or redispersed in water or another suitable liquid prior to being administered.

In a further preferred embodiment, the preparations are used for preparing medicinal products having controlled active substance release. To this end, they must generally be further modified, i.e. mixed with further auxiliary substances or enclosed by these. For instance, capsules or tablets containing a preparation according to the present invention can be coated with a polymeric film which controls the release of the active agent or agents. These and further techniques for producing medicinal products with modified or controlled release of active substance are known to those skilled in the art.

A preparation according to the present invention is basically produced in a multi-step process which can be varied if necessary or complemented by further steps. Initially, a chitosan derivative is selected as carrier, taking into account the relative number and type of the charged groups of the active agent, which on account of the type and relative number of its charged groups is matched with the active substance in such a way that at a certain pH value an isoionic state or charge equalization can be achieved between active substance and carrier. This is generally the case if the net-charges of active substance and chitosan derivative are opposite and the calculated isoionic point is in a pH range that is physiologically acceptable and is not detrimental to the stability of the active substance.

In a further step, a colloidal aqueous solution is prepared from the chitosan derivative and the active substance, which on account of its polymer content and the viscosity resulting therefrom is a sol. It is of no importance here whether the active substance is added following or prior to dissolving the chitosan derivative, or whether a solution of the chitosan derivative and an independently prepared solution of the active substance are united.

In a further step, the pH of the aqueous sol is adjusted such that an isoionic state results. In the course of this pH shift a precipitation of the active substance may occur. It has turned out here that the particles do generally not exceed the colloidal or nanoparticulate size range.

The sol which has been thus prepared and adjusted to an isoionic state can be dried in a further process step. For this purpose, conventional drying methods, but preferably drying methods applying no or only little heat such as freeze drying, may be used.

AMENDED CLAIMS

1. Solid pharmaceutical preparation comprising at least one at least partially charged active substance, which active substance is present in the form of a nanosol in which the active substance is bonded to an oppositely charged chitosan derivative, said solid pharmaceutical preparation being produced by a process, wherein

- a chitosan derivative is selected according to the type and relative number of its charged groups and in coordination with the type and relative number of the charged groups of the active substance such that at a certain pH value an isoionic state or charge equalization between active substance and carrier can be achieved in the preparation,
- an aqueous sol containing the active substance is prepared from the chitosan derivative,
- the pH value of the aqueous sol is adjusted such that an isoionic state results, possibly with colloidal or nano-scale active substance particles precipitating, and
- the thus-adjusted aqueous sol is dried.

2. Solid pharmaceutical preparation according to Claim 1, characterized in that the active substance possesses a positive charge and is bonded to a zwitterionic, acidic chitosan derivative.

3. Solid pharmaceutical preparation according to Claim 1, characterized in that the active substance possesses a negative charge and is bonded to a basic chitosan derivative.

4. Solid pharmaceutical preparation according to any one of the preceding claims, characterized in that the active substance and the chitosan derivative are present in the nanosol in almost isoionic state.

5. Solid pharmaceutical preparation according to any one of the preceding claims, characterized in that the active substance is present in the nanosol in colloidal or in nanoparticulate form.

6. Solid pharmaceutical preparation according to any one of the preceding claims, characterized in that the active substance is poorly soluble.

7. Solid pharmaceutical preparation according to any one of the preceding claims, characterized in that it contains a further polymeric carrier substance apart from the chitosan derivative.

8. Use of a pharmaceutical preparation according to any one of the preceding claims for the production of a medicinal product.

9. Use of a pharmaceutical preparation according to Claim 8 for the production of a medicinal product for peroral application.

10. Use of a pharmaceutical preparation according to any one of Claims 8 or 9 for the production of a medicinal product that is administered as a powder, granulate, tablet or capsule.

11. Use of a pharmaceutical preparation according to any one of Claims 8 to 10 for the production of a medicinal product which, for the purpose of administration, is dissolved or redispersed in a liquid.

12. Use of a pharmaceutical preparation according to any one of Claims 8 to 11 for the production of a medicinal product having controlled active substance release.

13. Use of a pharmaceutical preparation according to any one of Claims 1 to 7 for the production of a diagnostic agent.

14. Process for the production of a pharmaceutical preparation according to any one of Claims 1 to 7, characterized in that

a) a chitosan derivative is selected according to the type and relative number of its charged groups and in coordination with the type and relative number of the charged groups of the active substance such that at a certain pH value an isoionic state or charge equalization between active substance and carrier can be achieved in the preparation,

b) an aqueous sol containing the active substance is prepared from the chitosan derivative,

c) the pH value of the aqueous sol is adjusted such that an isoionic state results, possibly with colloidal or nano-scale active substance particles precipitating, and

d) the thus-adjusted aqueous sol is dried.

ABSTRACT

The invention relates to solid pharmaceutical preparations comprising at least one at least partially charged active substance in the form of a nanosol wherein the active substance is bonded to an oppositely charged chitosan derivative, processes for their production, and their use for the production of medicinal products.

3868-0109P
Attorney Docket No.

BIRCH, STEWART, KOLASCH & BIRCH, LLP

P.O. Box 747 • Falls Church, Virginia 22040-0747
Telephone. (703) 205-8000 • Facsimile: (703) 205-8050

PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT AND DESIGN APPLICATIONS

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Insert Title: PHARMEUTICAL PREPARATION CONTAINING NANOSOL

Fill in Appropriate Information - For Use Without Specification Attached:

the specification of which is attached hereto. If not attached hereto,
the specification was filed on _____ as
United States Application Number _____;
and amended on _____ (if applicable) and/or
the specification was filed on August 14, 2000 as PCT
International Application Number PCT/EP 00/07904, and was
amended on September 18th, 2001 (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representative or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Insert Priority Information: (if appropriate)

Prior Foreign Application(s)			Priority Claimed	
199 40 794.0 (Number)	Germany (Country)	August 27, 1999 (Month/Day/Year Filed)	☒ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional applications(s) listed below.

Insert Provisional Application(s): (if any)

(Application Number) (Filing Date)

(Application Number) (Filing Date)

All Foreign Applications, if any, for any Patent or Inventor's Certificate Filed More than 12 Months (6 Months for Designs) Prior to the Filing Date of This Application:

Insert Requested Information: (if appropriate)

Country	Application Number	Date of Filing (Month/Day/Year)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States and/or PCT application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States and/or PCT application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Insert Prior U.S. Application(s): (if any)

(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)
(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)

3868-0109P
Attorney Docket No.

I hereby appoint the practitioners at **CUSTOMER NO. 2292** as my attorneys or agents to prosecute this application and/or an international application based on this application and to transact all business in the United States Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the practitioners, unless the inventor(s) or assignee provides said practitioners with a written notice to the contrary:

Send Correspondence to:

BIRCH, STEWART, KOLASCH & BIRCH, LLP or **CUSTOMER NO. 2292**
P.O. Box 747 • Falls Church, Virginia 22040-0747
Telephone: (703) 205-8000 • Facsimile: (703) 205-8050

PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First or Sole Inventor: Insert Name of Inventor Insert Date This Document is Signed →

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Hans-Rainer HOFFMANN		13.02.2002
Residence (City, State & Country)		CITIZENSHIP
Burghofstr. 123, 56566 Neuwied, Germany DEX		German
MAILING ADDRESS (Complete Street Address including City, State & Country)		
Burghofstr. 123, 56566 Neuwied, Germany		

Insert Residence Insert Citizenship →

Insert Post Office Address →

Full Name of Second Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Bodo ASMUSSEN		13.02.2002
Residence (City, State & Country)		CITIZENSHIP
Im Schloßgarten 10, 56170 Bendorf-Sayn, Germany DEX		German
MAILING ADDRESS (Complete Street Address including City, State & Country)		
Im Schloßgarten 10, 56170 Bendorf-Sayn, Germany		

Full Name of Third Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

Full Name of Fourth Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

Full Name of Fifth Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

Full Name of Sixth Inventor, if any: see above

GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	DATE*
Residence (City, State & Country)		CITIZENSHIP
MAILING ADDRESS (Complete Street Address including City, State & Country)		

*DATE OF SIGNATURE